

**THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

**CERTIFICATION OF SETH
A. GOLDBERG, ESQ.**

SETH A. GOLDBERG, ESQ., being of full age, certifies as follows:

1. I am a Partner at Duane Morris LLP, attorneys for Defendants Zhejiang Huahai Pharmaceutical Co, Ltd., Princeton Pharmaceutical Inc., and Solco Healthcare US, LLC. I am also Liaison Counsel for all Defendants in this MDL. I make this Certification based on personal knowledge and in support of the Defendants' Memorandum of Law in Opposition to Plaintiffs' Motion to Preclude Opinions of Defense Expert Michael B. Bottorff, Pharm.D.

2. Attached hereto as Exhibit A is a true and accurate copy of the Expert Report of Michael B. Bottorff, dated August 2, 2021, with exhibits A (CV) and B (List of Materials Considered updated 9/24/21) served in MDL 2875.

3. Attached hereto as Exhibit B is a true and accurate copy of the transcript of the deposition of Michael B. Bottorff, Pharm.D., in MDL 2875, dated September 16, 2021, with errata.

4. Attached hereto as Exhibit C is a true and correct copy of Diaz Gomez, et al., The Absorption and Metabolism in Rats of Small Oral Doses of Dimethlnitrosamine, Biochem. J., 164, 497-500 (1977).

5. Attached hereto as Exhibit D is a true and correct copy of Liteplo, RG, et al., Concise International Chemical Assessment Document 38, N-Nitrosodimethylamine (2002).

6. Attached hereto as Exhibit E is a true and correct copy of Swenberg JA, Hoel DG, Magee PN (1991), Mechanistic and statistical insight into the large carcinogenesis bioassays on N-nitrosodiethylamine and N-nitrosodimethylamine. Cancer research, 51:6409–6414

7. Attached hereto as Exhibit F is a true and correct copy of portions of the 8/17/21 deposition transcript of Stephen Hecht, Ph.D.

8. Attached hereto as Exhibit G is a true and correct copy of portions of the 8/13/21 deposition transcript of Stephen Lagana, M.D.

9. Attached hereto as Exhibit H is a true and correct copy of portions of the 9/10/21 deposition transcript of Dipak Panigrahy, M.D.

10. Attached hereto as Exhibit I is a true and correct copy of Thelen K et al., Cytochrome P450-mediated metabolism in the human gut wall, J. Pharm. Pharmacol. 61:541-558 (2009).

11. Attached hereto as Exhibit J is a true and correct copy of Kushida H, et al., Metabolic activation of N-alkylnitrosamines in genetically engineered salmonella typhimurium expressing CYP2E1 or CYP2A6 together with human NADPH-cytochrome P450 reductase, Carcinogenesis 21(6):1227-32 (2000).

12. Attached hereto as Exhibit K is a true and correct copy of Pegg AE, Metabolism of N-nitrosodimethylamine, IARC Sci Publ. (27):3-22 (1980).

13. Attached hereto as Exhibit L is a true and correct copy of Relevance of N-nitroso compounds to human cancer: exposures and mechanisms. IARC Sci Publ. 1987;(84):150-152. PMID: 3679342.

14. Attached hereto as Exhibit M is a true and correct copy of Pegg et al., Alkylation of Nucleic Acids and Metabolism of Small Doses of Dimethylnitrosamine in the Rat, Cancer Research 41, 3128-3132 (1981).

15. Attached hereto as Exhibit N is a true and correct copy of Peto R et al., Effects on 4080 Rats of Chronic Ingestion of Nitrosodiethylamine or N-Nitrosodimethylamine: A detailed dose response study, Cancer Research 51:6415-6451 (1991).

16. Attached hereto as Exhibit O is a true and correct copy of Brantom P.G., Dose-Response Relationships in Nitrosamine Carcinogenesis, The British Industrial Biological Research Association (BIBRA) (1983).

17. Attached hereto as Exhibit P is a true and correct copy of Ito N et al., Induction of preneoplastic and neoplastic lesions in rats treated N-nitroso compounds, N-Nitroso Compounds: Occurrence and Biological Effects, (41):597-601 (1982).

18. Attached hereto as Exhibit Q is a true and correct copy of Pegg, Alkylation of rat liver DNA by dimethylnitrosamine: effect of dosage on O6 -methyl guanine levels. J. Natl Cancer Inst., 54, 681-687 (1977).

19. Attached hereto as Exhibit R is a true and correct copy of Pegg, A.E., Formation and subsequent repair of alkylation lesions in tissues of rodents treated with nitrosamines. Arch. Toxicol. (1979).

20. Attached hereto as Exhibit S is a true and correct copy of Pegg & Hui, Formation and subsequent removal of O6-methylguanine from DNA in rat liver and kidney after small doses of dimethylnitrosamine. Biochem. J., 173, 739-748 (1978).

21. Attached hereto as Exhibit T is a true and correct copy of Mass of an Adult, Physics Fact Book, Univ. of Ark. (2003).

22. Attached hereto as Exhibit U is a true and correct copy of WHO Europe Statement on Nutrition (2021).

23. Attached hereto as Exhibit V is a true and correct copy of Fine, D.R., Ross, R., Rounbehler, D.P., Silvergleid, A. & Song, L. (1977) Formation in vivo of

volatile N-nitrosamines in man after ingestion of cooked bacon and spinach. Nature, 265, 753-755.

24. Attached hereto as Exhibit W is a true and correct copy of Lakritz, L., Simenhoff, M.L., Dunn, S.R. & Fiddler, W. (1979) N-Nitrosodimethylamine in human blood, Fd Cosmet, Toxicol. Vol. 18, 77-79.

25. Attached hereto as Exhibit X is a true and correct copy of Elder. Tolerability of risk: A commentary on the nitrosamine contamination issue, J. Pharm. Sci. 000 (2021) 1-18.

Respectfully submitted,

/s/ Seth A. Goldberg

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